

coverage in this application on certain preferred embodiments of the invention. Accordingly, Applicants submit herewith new Claims 38-52 (Tab A), which cover particularly preferred embodiments of their invention. New Claims 38 and 39 are directed to specific humanized rabbit cholesteryl ester transfer protein (CETP) molecules. Claims 40-52 are directed to methods of achieving an anti-atherogenic blood component profile in a mammal. In particular, each of the methods of Claims 40-52 comprises the step of administering to a mammal a whole, non-endogenous CETP in an amount effective to achieve a desirable level of a specified component in the blood of the mammal.

Applicants have also canceled originally filed Claims 1-37, but reserve the right to prosecute these canceled claims in a subsequent divisional application to obtain the fullest extent of patent coverage to which Applicants are entitled.

Entry of the foregoing amendment prior to examination on the merits is respectfully requested.

Respectfully submitted,

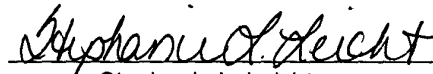


Leon R. Yankwich (Registration No. 30,237)
Thomas R. Berka, Ph.D. (Registration No. 39,606)
Attorneys for Applicant
YANKWICH & ASSOCIATES
130 Bishop Allen Drive
Cambridge, Massachusetts 02139
telephone: (617) 491-4343
telefax: (617) 491-8801

CERTIFICATE OF MAILING

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service as First Class mail, in an envelope addressed to the Asst. Commissioner for Patents, Washington, DC 20231, on the date indicated below.

July 6, 2001
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Stephanie L. Leicht

Complete Set of Substitute Claims Pursuant to 37 C.F.R. § 1.121(c)(3)

38. A humanized rabbit cholesteryl ester transfer protein comprising the amino acid sequence of SEQ ID NO:5.

39. A humanized rabbit cholesteryl ester transfer protein comprising the amino acid sequence of SEQ ID NO:6.

40. A method of modulating the level of endogenous, active cholesteryl ester transfer protein (CETP) in a mammal comprising administering to the mammal a whole, non-endogenous CETP in an amount effective to reduce CETP activity below 20% of that of the untreated mammal.

41. A method of modulating the level of endogenous cholesteryl ester transfer protein (CETP) in a mammal comprising administering to the mammal a whole, non-endogenous CETP in an amount effective to achieve a level of essentially 0 μ g of CETP per milliliter of blood of the mammal.

42. A method of modulating the level of HDL-cholesterol in a mammal comprising administering to the mammal a whole, non-endogenous cholesteryl ester transfer protein in an amount effective to achieve a lipoprotein profile wherein greater than about 90% of the total cholesterol in the blood of the mammal is HDL-cholesterol.

43. The method of modulating the level of HDL-cholesterol in a mammal according to Claim 42, wherein the mammal is administered a whole, non-endogenous cholesteryl ester transfer protein in an amount effective to achieve a lipoprotein profile wherein about 100% of the total cholesterol in the blood of the mammal is HDL-cholesterol.

44. A method of modulating the level of LDL-cholesterol in a mammal comprising administering to the mammal a whole, non-endogenous cholesteryl ester transfer protein in an amount effective to achieve a lipoprotein profile wherein less than about 10% of the total cholesterol in the blood plasma of the mammal is LDL-cholesterol.

45. A method of modulating the level of LDL-cholesterol in a mammal comprising administering to the mammal a whole, non-endogenous cholesteryl ester transfer protein in an amount effective to achieve a lipoprotein profile wherein essentially none of the total cholesterol in the blood of the mammal is LDL-cholesterol.

46. The method according to any one of Claims 40-45, wherein the mammal is a human.

a 47. The method according to any one of Claims 40-45, wherein the whole, non-endogenous cholesteryl ester transfer protein (CETP) is selected from the group consisting of a xenogeneic CETP; an allelic variant of the mammal's endogenous CETP; and a mammalianized, non-endogenous CETP in which the amino acid sequence of a non-endogenous CETP has been altered by deletion or substitution of one or more amino acids so as to make the amino acid sequence of said non-endogenous CETP more similar to the mammal's endogenous CETP.

48. The method according to Claim 47, wherein the mammal is a human.

49. The method according to any one of Claims 40-45, wherein the whole, non-endogenous cholesteryl ester transfer protein (CETP) is administered to the mammal by administering a plasmid-based vaccine comprising a promoter sequence suitable for directing the transcription of a nucleotide sequence in a cell of the mammal operably linked to a nucleotide sequence coding for the whole, non-endogenous CETP, wherein the plasmid-based vaccine expresses the whole, non-endogenous CETP in an amount effective to modulate the level of endogenous CETP, the level of LDL-cholesterol, or the level of HDL-cholesterol in the blood.

50. The method according to Claim 49, wherein the mammal is a human.

51. The method according to any one of Claims 40-45, wherein the whole, non-endogenous CETP is administered to the mammal in combination with an adjuvant, wherein the adjuvant is effective to non-specifically stimulate the immune response of the mammal.

52. The method according to Claim 51, wherein the adjuvant is selected from the group consisting of alum, Freund's Complete Adjuvant, Freund's Incomplete Adjuvant, and RIBI Adjuvant System.

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